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10/536,685	11/30/2005	Stefan Heckl	03528.0147.PCUS00	4627

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EXAMINER	
JONES, DAMERON LEVEST	

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1618	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/536,685	HECKL ET AL.	
	Examiner	Art Unit	
	D L. Jones	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *1/4/10 & 5/27/05*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11 and 17-21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11 and 17-21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *27 May 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *1/4/10 & 5/4/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

ACKNOWLEDGMENTS

1. The Examiner acknowledges receipt of the amendment filed 5/27/05 wherein the specification and claims were amended. In addition, the Examiner acknowledges receipt of the amendment filed 1/4/10 wherein claims 4, 5, and 7 were amended; claims 12-16 were canceled; and claims 17-21 were amended.

Note: Claims 1-11 and 17-21 are pending.

APPLICANT'S INVENTION

2. The instant invention is directed to a conjugate comprising an amphiphilic transport peptide of human origin, a nuclear localization sequence covalently coupled to the transport peptide, and a signaling and/or drug carrying module.

RESPONSE TO APPLICANT'S ELECTION

3. Applicant's election of Group I, drawn to conjugate compositions, in the reply filed on 1/4/10 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Thus, the restriction requirement is still deemed proper and is therefore made FINAL.

In addition, the Examiner acknowledges Applicant's election of the species wherein the transmembrane module is homeobox protein HOX-B1 (Sequence ID No. 1), the nuclear localization sequence is PKKKRKV (Sequence ID No. 3), and the signaling module is gadolinium. Initially, Applicant's elected species was searched. However, no prior art was found which could be used to reject the claims. Thus, the search was expanded over the full scope of Group I.

Note: It is duly noted that in response to the Examiner's restriction requirement, Applicant canceled all of the method of uses claims and added product claims containing the intended use of each of the canceled method claims. However, Applicant is first reminded that the patentability of a product claim is based upon the components present in the product, not the intended use of the product. Method claims containing the use of the product are the proper manner in which to claim the various uses of a product. Thus, since claims 17-21 are directed to products of claim 1, the claims will be analyzed based on the components of the product, not the intended use of the product.

DOUBLE PATENTING REJECTIONS

4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422

F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Claims 1, 2, 5-10, and 17-21 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-16 of U.S. Patent No. 7,531,502. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are directed to conjugates having a transmembrane module, a spacer, an address mo0dule (localization sequence module), and a signaling module. The claims differ in that those of the patented invention read on specific cell penetrating human transmembrane peptides in combination with a specific signaling module (gadolinium) whereas the instant invention is not limited to any particle transmembrane module or signaling module. Thus, a skilled artisan would recognize that the instant invention encompasses the patented invention because the two invention disclose overlapping subject matter.

6. Claims 1, 5, 6, 10, 11, and 17-21 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-4 and 6 of U.S. Patent No. 7,563,761. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are directed to conjugates comprising a transport peptide, a nucleus recognition signal peptide, and a 'drug' module. The claims differ in that the transport peptide of the patent is not necessarily limited to those of human origin. In addition, the claims differ in that the peptide nuclear acid moiety of the patented invention function as the drug in the instant invention because it is the component in the patented invention that hybridizes to DNA of HIV and inhibits the transcription thereof. Hence, the skill artisan would recognize that the instant invention encompasses the patented invention because the two inventions contain overlapping subject matter.

7. Claims 1, 5-8, 10, 11, and 17-21 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-10, 19, and 20 of U.S. Patent No. 6,821,948. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are directed to conjugates comprising a transmembrane specific peptide, an address protein (location sequence module), and an active substance. The claims differ in that the patented transmembrane peptide is not necessarily of human origin and the patented claims do not disclose a specific active substance/substance. However, the skilled artisan would recognize that the active substance encompasses drugs based on the patented

disclosure (e.g., see Figure 5 of the patent). Thus, the skilled artisan would recognize that the inventions disclose overlapping subject matter.

8. Claims 1, 2, 5, 6, 9, 10, and 17-21 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3, 6-8, 11, 13-16, 19, and 21 of copending Application No. 12/634,972. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are directed to a composition comprising a transport component (i.e., a peptide), a nuclear localization sequence module, and a signaling module. The claims differ in that the copending application does not specify that the transport peptide is of human origin. However, the skilled artisan would recognize that the claims of the copending application encompasses those of the instant invention because the inventions disclose overlapping subject matter.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

112 FIRST PARAGRAPH REJECTIONS (Written Description)

9. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10. Claims 1-11 and 17-21 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably

convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant is reminded that an Inventor is entitled to a patent to protect his work only if he/she produces or has possession of something truly new and novel. The invention being claimed must be sufficiently concrete so that it can be described for the world to appreciate the specific nature of the work that sets it apart from what was before. The Inventor must be able to describe the item to be patented with such clarity that the Reader is assured that the Inventor actually has possession and knowledge of the unique composition that makes it worthy of patent protection. The instant application does not sufficiently describe the invention as it relates to the following: (1) what amphiphilic transport peptides of human origin Applicant is referring to that is compatible with the instant invention; (2) nuclear localization sequence or sequences are compatible with the instant invention; (3) what drug/drugs and signaling module/modules may be used with the instant invention; (4) what conjugate combination is compatible with the instant invention; (5) what human homeobox protein HOX-B1 derivatives Applicant is referring to that are compatible with the instant invention and which derivatives are useful with various conjugate combinations; (6) what (a) signaling modules and drug module are compatible; (b) what signaling module, drug module, compound, and non-cleavable spacer II drug module combination is compatible with the instant invention; (7) what signaling module, drug module, compound trapping the signal module, compound trapping the drug module, additional signaling module, and additional drug module Applicant is referring to that are

compatible with the claims; (8) what combination of the components will yield the desired result; (9) what compounds for trapping Applicant is referring to that are compatible with the instant invention; and (10) what additional components are required for the products of claims 17-21 to function as set forth in the respective claims. The claims encompass a genus of unspecified components (i.e., transport peptides, nuclear localization sequences, drugs, signaling modules, human homeobox protein derivatives, trapping compounds, spacers, cytotoxic drugs, etc.). Review of the disclosure does not provide sufficient description of the various components. For example, on pages 5-6, the term 'derivative' sets forth that one or more of the amino acids in the homeobox protein is substituted, deleted, or an addition(s) has occurred at one or multiple locations, but the disclose does not set for all possible combinations that are combinable with other components of the conjugates or possible combinations that have such modifications that yield the desired results. On page 6, lines 7-12, the transmembrane module is defined as being produced biologically. On pages 6-7, the signaling and drug module is defined as not subject to any limitations, but may be chosen freely depending on the effect that is produced in the cell. While the specification gives a few specific conjugate component combinations (see page 18, Table 1), the disclosure is not such that a skilled artisan would know what combination or even components are appropriate and useful with the instant invention. As a result, what the Reader gathers from the instant application is a desire/plan/first step for obtaining a desired result. While the Reader can certainly appreciate the desire for

achieving a certain end result, establishing goals does not necessarily mean that an invention has been adequately described.

While compliance with the written description requirements must be determined on a case-by-case basis, the real issue here is simply whether an adequate description is necessary to practice an invention described only in terms of its function and/or based on a disclosure wherein a description of the components necessary in order for the invention to function are lacking. In order to satisfy the written description requirement, the specification must describe every element of the claimed invention in sufficient detail so that one of ordinary skill in the art would recognize that the Inventor possessed the claimed invention at the time of filing. In other words, the specification should describe an invention and does so in sufficient detail that one skilled in the art can clearly conclude that the Inventor created what is the claimed. Thus, the written description requirement is lacking in the instant invention since the various terms as set forth above are not described in a manner to clearly allow persons of ordinary skill in the art to recognize that Applicant invented what is being claimed.

112 SECOND PARAGRAPH REJECTIONS

11. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

12. Claims 1-11 and 17-21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-11 and 17-21: The claims as written is ambiguous because it is unclear what amphiphilic transport peptides of human origin Applicant is referring to that is compatible with the instant invention. Likewise it is unclear what nuclear localization sequence or sequences and the drug/drugs and signaling module/modules that may be used with the instant invention. Furthermore, the claim is ambiguous because it is unclear what conjugate combination is compatible with the instant invention. In addition, the claims are ambiguous because of the 'and/or' appearing in the claim. Specifically, it is unclear what components are necessary for each conjugate composition combination to be operable.

Claim 3: The claim as written is ambiguous because it is unclear what human homeobox protein HOX-B1 derivatives Applicant is referring to that are compatible with the instant invention and which derivatives are useful with various conjugate combinations.

Claim 6: The claim as written is ambiguous because of the 'and/or' phrases. In particular, it is unclear what (a) signaling modules and drug module are compatible; (b) what signaling module, drug module, compound, and non-cleavable spacer II drug module combination is compatible with the instant invention. Also, the claim is indefinite because it is unclear what compound (see line 2) that Applicant is referring to.

Claim 10: The claim is ambiguous for various reasons. First, it is unclear what signaling module, drug module, compound trapping the signal module, compound trapping the drug module, additional signaling module, and additional drug module Applicant is referring to that are compatible with the claims. In addition, it is unclear

what combination of the components will yield the desired result. Furthermore, the claims are confusing because it is unclear what compounds for trapping Applicant is referring to that are compatible with the instant invention.

Claims 17-21: The claims as written are ambiguous because the claims are product claims but do not contain any additional components to further limit the conjugate of claim 1.

Claims 17-21 provide for the use of the conjugate of claim 1, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

13. Claims 17-21 rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: the steps necessary in order for the conjugates to (a) be a diagnostic composition for cell tracking; (b) be a contrast agent for MRI; (c) the steps necessary for the diagnostic composition to determine the activity of DNA repair enzymes; (d) be a pharmaceutical composition for the chemotherapeutical treatment of a tumor; and (e) be a pharmaceutical composition for the intranuclear GNCT-treatment of a tumor.

101 REJECTIONS

14. Claims 17-21 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd. App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

COMMENTS/NOTES

15. It should be noted that no prior art is cited against the instant invention. However, Applicant MUST address and overcome the double patenting and 112 rejections.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to D L. Jones whose telephone number is (571)272-0617. The examiner can normally be reached on Mon.-Fri., 6:45 a.m. - 3:15 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should

you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/D L. Jones/
Primary Examiner
Art Unit 1618

March 24, 2010